Attorney's Docket No. 3135 R1



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Chen et al.)		
Serial No:	10/606,969) Group Art (Unit:	Unassigned
Filed:	06/25/03) Examiner:	Unas	signed
For: SHORT DURA))			
		_)		

Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313

INFORMATION DISCLOSURE STATEMENT

Sir:

Applicants submit herewith patents, publications and other information of which they are aware, which they believe an examiner may consider to be material to the patentability of the claims of this application, and in respect of which there may be a duty to disclose in accordance with 37 C.F.R. § 1.56.

While this Information Disclosure Statement may contain "material" information pursuant to 37 C.F.R. § 1.56, it is not intended to constitute an admission that any patent, publication or other information referred to herein is either "material" or "prior art" to the invention dis closed and claimed in the above-referenced application unless specifically designated as such. Applicants specifically reserve the right, where appropriate, to avoid or antedate any such reference by the appropriate arguments or showings under 37 C.F.R. § 1.131 and § 1.608, or any other appropriate means.

A completed PTO Form 1449 listing each reference which is not a U.S. Patent application is submitted herewith, and it respectfully requested that an Examiner initialed copy of the PTO Form 1449 be returned to the undersigned.

A copy of each reference therein listed accompanies this Information Disclosure Statement.
-OR-
NO copies of the references therein listed accompany this Information Disclosure Statement under
37 C.F.R. § 1.98(d), as each was previously cited by or submitted to the Patent Office in prior

application Serial No. 09/129,687, filed 08/05/98, which this application relies upon for an earlier filing date under 35 U.S.C. § 120.

This Information Disclosure Statement is not a representation that a search has been made or that no other information material to the patentability of this invention exists.

[]	This Information Disclosure Statement is being filed within three months of the filing or entry of the national stage of this application, or before the mailing of a first Office Action on the merits, whicheve is later. No fee is required under 37 C.F.R. § 1.97(b). However, in the event that more than 90 days from filing have elapsed and a first Office Action on the merits has been mailed, the Commissioner is hereby authorized to charge the fee required under 37 C.F.R. 1.17(p) to Deposit Account Number 01-1173.
\boxtimes	This Information Disclosure Statement is being submitted <i>after</i> three months from the date of filing or entry of the national stage or this application, or <i>after</i> the mailing of a first Office Action, whichever is later, but <i>before</i> the mailing date of either a final Office Action or a Notice of Allowance.
	The Commissioner is hereby authorized to charge the fee required under 37 C.F.R. § 1.17(p) to Deposit Account 10-0750. -OR-
	Certification as specified in 37 C.F.R. § 1.97(e) follows:
	Each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application no more than three months prior to the filing of this statement.
	No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned, after making reasonable inquiry, was known to any individual designated in § 1.56(c) more than three months prior to the filing of this

Information Disclosure Statement.

The Examiner is hereby requested to consider these references and other information and make them of record in the above-referenced application. Applicants respectfully submit that the claims of this application are patentable over the above-cited references and information. Examination and allowance of this application at an early date are requested.

Respectfully submitted,

Date: 10/8/03

Samuel E. Webb, Reg. No. 44,394

ALZA Corporation c/o Johnson & Johnson 1 Johnson & Johnson Plaza, WH 3221 New Brunswick, NJ 08933 Tel. 650-564-5106

Fax. 650-564-2195

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, Alexandria, VA 22313 on October 2, 2003.

ALZA CORPORATION

BY: Yolauto Peuce

Johanna Pence

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Sheet 1 of 1

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ATTORNEY'S DOCKET NO.: APPLICATION NO.: ARC 3135 R1 10/606,969

APPLICANT:

Chen et al.

FILING DATE: GROUP:

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	US PATENT D		I.		
		NAME	CLASS	SUBCLAS S	FILING DATE
			128	260	12/27/72
		et al.	264	49	6/7/74
10/26/76	987,790 10/26/76 Ecker	hoff et al.	128	260	10/1/75
2/22/77	008,719 2/22/77 Theeu	wes et al.	128	260	2/2/76
4/17/84	443,340 4/17/84 May e	t al.	210	697	5/24/83
2/4/86	586,559 2/4/86 Nuwa	yser et al.	427	3	2/6/84
11/18/86	623,588 11/18/86 Nuwa	yser et al.	428	402.24	12/2/85
5/26/87	668,506 5/26/87 Bawa	-	424	429	8/16/85
11/24/87	708,861 11/24/87 Popes	cu et al.	424	1.1	1/31/85
12/8/87	711,782 12/8/87 Okada	ı et al.	424	455	12/11/86
12/15/87	713,244 12/15/87 Bawa	et al.	424	429	8/16/85
8/1/89	853,218 8/1/89 Yim e	al.	424	85.7	2/24/87
9/12/89	865,845 9/12/89 Ecken	hoff et al.	424	424	9/12/89
9/12/89	866,050 9/12/89 Ben-A	moz	514	179	4/27/88
6/5/90	931,279 6/5/90 Bawa	et al.	424	427	7/21/88
7/3/90	938,763 7/3/90 Dunn	et al.	604	891.1	10/03/88
1/15/91	985,404 1/15/91 Mitch	ell et al.	514	6	6/29/88
5/28/91	019,400 5/28/91 Gomb	otz et al.	424	497	5/1/89
10/15/91	057,318 10/15/91 Magru	ider et al.	424	438	4/23/90
10/22/91	059,423 10/22/91 Magru	der et al.	424	438	4/23/90
10/29/91	061,492 10/29/91 Okada	et al.	424	423	1/24/90
12/31/91	077,033 12/31/91 Viegas	s et al.	514	668	8/7/90
2/4/92	085,866 2/4/92 Cows	ar et al.	424	481	12/2/88
5/12/92	112,614 5/12/92 Magru	der et al.	424	422	9/14/89
8/11/92	137,727 8/11/92 Ecken	hoff et al.	424	422	6/12/91
9/29/92	151,093 9/29/92 Theeu	wes et al.	604	892.1	10/29/9
1/26/93	181,914 1/26/93 Zook		604	307	5/6/92
5/11/93	209,746 5/11/93 Balab	an et al.	604	892.1	2/18/92
8/10/93	234,692 8/10/93 Magru	der et al.	424	473	9/2/92
	151,093 181,914 209,746	9/29/92 Theeu 1/26/93 Zook 5/11/93 Balaba	9/29/92 Theeuwes et al. 1/26/93 Zook 5/11/93 Balaban et al. 8/10/93 Magruder et al.	9/29/92 Theeuwes et al. 604 1/26/93 Zook 604 5/11/93 Balaban et al. 604	9/29/92 Theeuwes et al. 604 892.1 1/26/93 Zook 604 307 5/11/93 Balaban et al. 604 892.1 8/10/93 Magruder et al. 424 473

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INFORMATION DISCLOS	ATTORNEY'S DOCKET NO.:		CATION NO.	:	
CITATION Chart 1 of 2	ARC 3312 R1	10/606,969			
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5,234,693	8/10/93	Magruder et al.	424	473	9/2/92
5,242,910	9/7/93	Damanj	514 424	152	10/13/92
5,252,318	10/12/93			78.04	6/15/90
5,278,201	1/11/94	Dunn et al.	523 604	133	4/24/90
5,279,608	1/18/94	1/18/94 Cheikh		892.1	12/4/91
5,308,348	5/3/94	Balaban et al.	644	891.1	5/5/93
5,310,865	5,310,865 5/10/94		528	361	12/18/92
5,324,519	6/28/94	Dunn et al.	424	426	10/28/91
5,300,295	8/5/94	Viegas et al.	424	427	9/13/91
5,336,057	8/9/94	3/9/94 Toshio Fukuda et al.		395	7/20/93
5,330,452	7/19,94	/19,94 Zook		307	6/1/93
5,340,614	8/23/94	/94 Perman et al.		2.24	2/11/93
5,342,627	8/30/627	30/627 Chopra et al.		473	11/12/92
5,415,866	5/16/95	95 Zook		448	7/12/93
5,540,912	7/30/96	/96 Roorda et al.		422	3/30/93
5,441,732	8/15,95	5,95 Hoeg et al.		78.04	3/18/92
5,447,725	9/5/95	Damani et al.		435	6/11/93
5,456,679	10/10/95	0/10/95 Balaban et al.		892.1	12/7/94
5,487,897	1/30/96	Polson et al.	424	426	9/28/93
5,540,912	7/30/96	30/96 Roorda et al.		422	7/30/96
5,543,156	8/6/96			484	1/21/94
5,556,905	9/17/96	7/96 Frappier et al.		311	3/30/94
5,571,525	11/5/96	Roorda et al.	424	426	3/30/94
5,787,175	12/24/96	Viegas et al.	424	427	12/28/93
5,599,534	2/4/97	Himmelstein et al.	424	78.04	8/9/94
5,599,552	2/4/97			423	5/26/94
5,610,184	3/11/97			540	3/3/95
5,618,563	4/8/97	Berde et al.	424	501	9/10/93
5,620,700 4/15/97		Berggen et al.	424	435	5/9/95
5,651,986 7/29/97		Brem et al.	424	484	6/14/96
5,654,010	8/5/97	Johnson et al.	424	502	7/7/95
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ATTORNEY'S DOCKET NO .: APPLICATION NO.: NFORMATION DISCLOSURE ARC 3312 R1 10/606,969 CITATION Sheet 1 of 3 APPLICANT: PTO-1449 Chen et al. FILING DATE: GROUP: 06/25/03 1615 **US PATENT DOCUMENTS** 5,656,297 8/12/97 Bernstein et al. 424 484 5/3/94 5,660,817 8/26/97 11/9/94 Masterman et al. 424 49 5,674,292 10/7/97 Tucker et al. 623 16 7/7/95 5,618,563 4/8/97 Berde et al. 424 501 9/10/93 5.681.873 10/28,97 Norton et al. 523 115 10/14/93 5,700,485 12/23/97 Berde et al. 424 501 5/1/95 1/13/98 434 5,707,664 Illum 424 12/20/94 5,708,011 1/13/98 330 10/13/94 Bardsley et al. 514 5,733,950 3/31/98 Dunn et al. 523 113 9/25/95 5,744,153 4/28/98 Yewey et al. 424 426 6/9/97 5,747,058 5/5/98 Tipton et al. 424 337 6/7/95 5.747,060 5/5/98 Sackler et al. 424 426 3/26/96 Yewey et al. 5,759,563 6/2/98 424 426 6/7/95 Shahinian Jr. 5,760,077 6/2/98 514 540 3/11/97 5,766,637 6/16/98 Shine et al. 424 497 10/8/96 5,780,044 7/14/98 Yewey et al. 424 426 12/5/96 5,783,205 7/21/98 Berggren et al. 424 426 4/10/97 5.804.212 9/8/98 Illum 424 434 6/17/97 5.849.763 12/15/98 Bardsley et al. 514 445 10/27/95 5.910. 502 6/8/99 514 330 3/3/98 Gennery 5,922,340 7/13/99 424 426 Berde et al. 9/16/96 5,942,241 8/24/99 Chasin et al. 424 426 6/7/96 5.955.479 9/21/99 330 10/13/94 Bardsley et al. 514 9/28/99 5.958.443 Viegas et al. 424 427 12/23/96 5,972,326 10/26/99 Galin et al. 424 78.04 3/18/97 5,972,366 10/26/99 Havnes et al. 424 422 9/17/96 11/23/99 5,990,194 Dunn et al. 523 113 11/7/97 5,919,835 7/6/99 Domb et al. 523 113 12/23/92 6,004,295 12/21/99 Langer et al. 604 164 6/26/98 6,046,187 4/4/00 Berde et al. 514 180 9/16/96 6.050.986 4/18/00 Hektner 604 508 12/1/97

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Sheet 4 of 6 ATTORNEY'S DOCKET NO .: APPLICATION NO.: NFORMATION DISCLOSURE ARC 3312 R1 10/606,969 CITATION Sheet 1 of 4 PTO-1449 APPLICANT: Chen et al. FILING DATE: GROUP: 06/25/03 1615 **US PATENT DOCUMENTS** 6,086,909 7/11/00 Harrison et al. 424 2/12/99 430 6,103,266 8/15/00 Tapolski et al. 424 484 4/22/98 6,106,301 8/22/00 Merril 434 262 9/4/97 6,117,425 9/12/00 McPhee et al. 424 94.64 7/7/95 6,120,789 9/19/00 Dunn 424 426 3/30/99 6,120,804 9/19/00 Drizen et al. 424 488 4/8/99 6,129,933 10/10/00 Oshlack et al. 424 495 7/24/97 6,130,200 10/10/00 Brodbeck et al. 2 514 12/18/97 6,136,334 10/24/00 Viegas et al. 424 427 6/11/97 Chandeashekar et al. 6,143,314 11/7/00 424 426 10/28/98 6,193,991 2/27/01 Shukla 424 426 10/28/98 6,193,994 2/27/01 Lee at al. 424 444 5/22/97 6,197,327 3/6/01 Harrison et al. 424 430 5/15/98 6,214,387 4/10/01 Berde et al. 424 501 9/17/97 6,217,911 4/17/01 Vaung et al. 424 501 7/5/96 6,238,702 5/29/01 Berde et al. 424 489 7/12/99 6,248,345 6/19/01 Goldenheim et al. 424 426 7/2/98 6,255,502 7/3/01 Penkler et al. 552 549 7/11/97 Bawa et al. 6.261.547 7/17/01 424 78.04 11/23/99 6,309,375 10/30/01 Glines et al. 604 187 5/18/99 6,322,548 11/27/01 Payne et al. 604 500 3/31/98 6,352,667 3/5/02 English 264 328.17 8/24/99 6,355,273 3/12/02 Carli et al. 424 489 8/4/00 6,372,245 4/16/02 Bowman et al. 424 427 4/22/94 6,375,659 4/24/02 Erbe et al. 606 94 2/20/01 6,395,293 5/28/02 Polson et al. 424 426 3/8/00 6,403,057 6/11/02 Schneider et al. 424 9.52 6/23/00 6,417,201 7/9/02 Bardsley et al. 514 330 7/12/00 6,426,339 7/30/02 Berde et al. 514 180 4/3/00 6,432,415 8/13/02 Osborne et al. 424 400 12/17/99

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Sheet 5 of 6 ATTORNEY'S DOCKET NO .: APPLICATION NO.: MFORMATION DISCLOSURE ARC 3312 R1 10/606,969 CITATION Sheet 1 of 5 PTO-1449 APPLICANT: Chen et al. FILING DATE: GROUP: 06/25/03 1615 **US PATENT DOCUMENTS** US 2001/0004644 A1 6/21/01 Levin 514 646 12/15/00 US 2001/0046518 A1 11/29/01 424 8/14/98 Sawhney 486 US 2001/0055607 A1 12/27/01 Levin 424 435 7/17/98 US 2002/0015712 A1 2/7/02 5/23/00 Mchride et al. 424 400 US 2002/0001608 A1 1/3/02 Polson et al. 424 426 3/8/00 US 2002/0010150 A1 514 1/24/02 Cortese et al. 54 4/26/01 US 2002/0016338 A1 2/7/02 Mather et al. 514 317 10/1/01 US 2002/0028243 A1 3/7/02 **Masters** 424 484 2/28/01 US 2002/0028181 A1 3/7/02 Miller et al. 424 43 4/26/01 US 2002/0037104 A1 11/1/01 Zhang et al. 604 502 2/28/01 US 2002/0037358 A1 3/28/02 427 Barry et al. 2.1 10/18/01 US 2002/0039594 A1 4/4/02 424 426 5/11/98 Unger US 2002/0004063 A1 1/10/02 Zhang 424 443 9/28/99 US 2002/0045668 A1 4/18/02 Dang et al. 514 649 7/17/01 US 2002/0054915 A1 5/9/02 Goldenheim et al. 424 4/2/01 497 US 2002/0061326 A1 5/23/02 424 Wei-Ping Li et al. 424 1/2/01 US 2002/0086971 A1 7/14/02 Pham 528 354 2/1/02 **FOREIGN PATENT DOCUMENTS** WO 93/24150 **PCT** WO 95/13799 PCT WO 98/27962 PCT WO 98/27963 PCT WO 99/47073 PCT WO 00/74650 A2 PCT WO 02/058670 A1 **PCT** WO 02/067991 A1 PCT WO 03/041685 A1 PCT WO 03/041684 A2 PCT WO 03/041757 A2 PCT OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages etc.) Cleland, J. L. "Injectable Gels for Local and Systemic Delivery of Proteins," Proceed, Int'l. Symp. Control. Rel. Bioact. Mater., Vol. 28, 2001, EXAMINER:

Examiner: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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a poly <u>Bioma</u>	(lactide-coglycolide) film: i <u>sterials,</u> Vol. 20, pp.1919-19	n vivo biocon 24, 1999.	npatibility and drug		
Int'l. S	Duenas, E. et al. "Sustained Delivery of rhVEGF from a Novel Injectable Liquid, Plad" Proceed. Int'l. Symp. Control. Rel. Bioact. Mater., Vol. 28, 2001.				
in plas	Guevello, P. Le at al. "High-performance liquid chromatographic determination of bupivacaine in plasma samples for biopharmaveutical studies and application to seven other local anaesthetics," <u>Journal of Chromatography</u> , Vol. 622, pp. 284-290, (1993).				
	Garry, M. G. et al. "Evaluation of the efficency of a bioerodible bupivacaine polymer system on antinociception and inflammatory mediator release," <u>Pain</u> , vol. 82, pp. 49-55, 1999.				
syster (1995)	Lambert, W. J. at al. "Development of an in situ forming bidegradable poly-lactide-co-glycolid system for controlled release of proteins," <u>Journal of Controlled Release</u> , Vol. 33, pp. 189-195 (1995).				
Okum Plad,"	Okumu, F. W. et al. "Sustained Delivery of Growth Hormone from a Novel Injectable Liquid, Plad," Proceed. Int'l. Symp. Control. Rel. Bioact. Mater., Vol. 28, 2001.				
Growt Contro	Okumu, F. W. et al. "Evaluation of the Saber™ Delivery System for Sustained Release of Growth Hormone – Formulation Design and <i>In Vivo</i> Assessment," <u>Proceed. Int'l. Symp. Control. Rel. Bioact. Mater.</u> , Vol. 28, 2001.				
	Philip, B. K. et al. "The Economoc Impact of Opioids on Postoperative Pain Management," <u>Journal of Clinical Anesthesia</u> , Vol. 14, pp. 354-364, 2002.				
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Examiner: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.